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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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EXAMINER

HAYES, R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1647

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DATE MAILED: 11/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/157,984

Applicant(s)
Lai et al

Examiner
Robert C. Hayes

Group Art Unit
1647



☒ Responsive to communication(s) filed on Aug 15, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) 2 and 5 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3, and 4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-5 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 1, 3 & 4) in Paper No. 9 is acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the remaining restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2 & 5 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected inventions. Election was made **without** traverse in Paper No. 9.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the post office address of each inventor. A post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The post office address should include the ZIP Code designation.

Double Patenting

3. Claim 4 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both

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cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Note that the instant claims are both products with identical claim language, except for the intended use language in claim 4 which otherwise carries no patentable weight in a product claim.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 & 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification solely describes carp NT-7 as depicted in SEQ. ID NO 1. No written description of any different NT-7 polypeptides that can be structurally envisioned by one skilled in the art (i.e., by amino acid sequence) are disclosed within the specification, including what structurally defines the genus of NT-7-related polypeptides. Thus, the skilled artisan would not know when they are in possession of the invention, as broadly claimed, based on the limited disclosure provided by the instant specification on only the murine sequence, because the skilled

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artisan cannot structurally visualizing what a generic NT-7 amino acid sequence constitutes; thereby, not meeting the written description requirements of 35 U.S.C. § 112, first paragraph.

5. Claims 1, 4 & 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the carp NT-7 polypeptide of SEQ ID NO: 1, or functional variants thereof that increase survival and neurite outgrowth of embryonic chick DRG neurons, does not reasonably provide enablement for NT-7 polypeptides with no recited structural nor functionally characteristics, nor any biologically functional equivalents of such without specific structural and functional characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The name "NT-7", alone, does not sufficiently characterize and enable the full scope of the polypeptides encompassed by the current claim language, because the inclusion of any "functional variants, analogues and functional fragments", or biologically functional equivalent thereof, within the definition of NT-7 polypeptides sets forth little structural and functional characteristics. In contrast, the specification does not teach which particular amino acids are critical for any NT-7's function, nor how to distinguish the essentially purified carp NT-7 polypeptide of the instant invention from any different protein molecule that possess none of the desired functions of the instant invention. In other words, such structurally deficient polypeptides containing random mutations/variations would be expected by the skilled artisan to result in inactive proteins. For

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example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for any NT-7 polypeptide function would prevent the skilled artisan from determining whether any modification or mutation to the single disclosed carp NT-7 molecule could be made which retains the desired function of the instant invention, because any random mutation or modification manifested within a NT-7 would be predicted to adversely alter its biologically active 3-dimensional conformation, without undue experimentation to determine otherwise.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3 & 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Lai et al.

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Lai et al. teach isolation of a carp NT-7 polypeptide that is 100% to SEQ ID NO:1. In that this polypeptide is contained in a composition comprising water, the limitations of claim 3 are met. It is noted that the functional limitations recited within claim 4 carry no patentable weight, as it relates to product claims. *In arguendo*, the functional limitations recited in claim 4 are inherent properties of Lai's NT-7 polypeptide; absent evidence to the contrary.

7. Claims 1, 3 & 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Nilsson et al.

Nilsson et al. teach isolation of a NT-7 polypeptide from zebrafish that is 92% identical to SEQ ID NO:1 (Fig. 1), and discloses fragments thereof (Fig. 2); thereby, reasonably meeting the limitations of a "functional variant, analogue and functional fragment of NT-7". In that this polypeptide is contained in a composition comprising water and DMEM (e.g., pgs 287-289; Fig. 3), the limitations of claim 3 are met. It is noted that the functional limitations recited within claim 4 carry no patentable weight, as it relates to product claims. *In arguendo*, the functional limitations recited in claim 4 are inherent properties of Nilsson's NT-7 polypeptide; absent evidence to the contrary. It should be noted that the four authors of Lai et al. are not equivalent to the inventive entity of the instant application.

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Conclusion

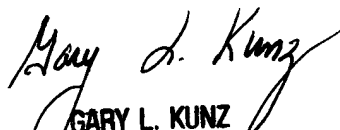
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
October 30, 2000



GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600